# EPA Registration Number 239-2721

# PROCESSING REQUEST

**Reg #** 239-2121 **Decision #** 515043

**Description:** Revise Alt A + B CSF

| **Electronic Label & Letter** (see PPLS): | **OR** | **Non Electronic Label & Letter** (Scanning required): |
|---|---|---|
| ☐ Dated: | | ☐ Dated: |

***Only one label type should be selected***

**Other Materials Sent** (see jacket):

☑ New CSF(s) Dated: 1-13-2016

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

**Reviewer: Angela Hollis**

**Division: RD**

**Phone: 347-0216** **Date:** 4-10-16

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 13, 2016

Chris Zemanek
Analyst
Registrations
The Ortho Group
P.O. Box 190
Marysville, OH 43040

Subject: CSF Notification per PRN 98-10 –Revise CSF Alt A and B
Product Name: ORTHO 13% BIFENTHRIN MUP
EPA Registration Number: 239-2721
Application Date: 3/7/2016
Decision Number: 515043

Dear Mr. Zemanek:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The CSFs submitted with your application have been stamped "Notification" and placed in our files.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 5/9/2013
- Alternate CSF A dated 1/13/2016
- Alternate CSF B dated 1/13/2016

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, please contact Angela Hollis at 703-347-0216 or by email at hollis.angela@epa.gov.

Sincerely,

Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

*The Scotts Company LLC*
*and Subsidiaries*

March 7, 2016

Mr. Kable Davis (PM-03)
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7505P)
Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

**SUBJECT:** **Product Chemistry Notification per PR Notice 98-10**
**Ortho 13% Bifenthrin MUP**
**EPA Reg. No. 239-2721**

Dear Mr. Davis:

The Scotts Company d/b/a The Ortho Group is submitting a Product Chemistry Notification to add alternate suppliers to the Alternate A and B Confidential Statement of Formulas (CSF) per PR Notice 98-10 for Ortho 13% Bifenthrin MUP, EPA Reg. No. 239-2721. The alternate suppliers are being added for the active ingredient. We are also deleting an active ingredient supplier as their registration in no longer active.

Please find the following documentation in support of this submission:



- Application of Pesticide Registration, Form 8570-1;
- Formulator's Exemption Statement, Form 8570-27;
- One (1) copy of the approved ALT A CSF dated 05/09/2013;
- One (1) copy of the approved ALT B CSF dated 05/09/2013;
- Two (2) copies of the proposed ALT A CSF dated 01/13/2016;
- Two (2) copies of the proposed ALT B CSF dated 01/13/2016.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula (except as noted) of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Please contact me at 937-578-1467 or by email at chris.zemanek@scotts.com should you have any questions regarding this submission.

Sincerely,

Chris Zemanek
Analyst, Regulatory Affairs
Enclosures

*Please read instructions on reverse before completing form.* Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

**EPA** United States **Environmental Protection Agency** Washington, DC 20460

☐ **Registration** ☐ **Amendment** ☒ **Other**

Identifier Number

## Application for Pesticide - Section I

| 1. Company/Product Number | 2. EPA Product Manager | 3. Proposed Classification |
|---|---|---|
| 239-2721 | Kable Davis | ☒ None ☐ Restricted |
| 4. Company/Product (Name) The Ortho Group/Ortho 13% Bifenthrin MUP | PM# PM-03 | |

5. Name and Address of Applicant *(Include ZIP Code)*
The Ortho Group
P.O. Box 190
Marysville, OH 43040
☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

## Section II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated
☒ Notification - Explain below.
☐ Final printed labels
☐ "Me Too" Application
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
Addition of active ingredient suppliers and deletion of one active ingredient supplier to Alternate A & B CSFs. See cover letter for additional details and certification statement.
Chris.Zemanek@scotts.com

## Section III

1. Material This Product Will Be Packaged In:

| Child-Resistant Packaging | Unit Packaging | Water Soluble Packaging | 2. Type of Container |
|---|---|---|---|
| ☐ Yes* ☐ No | ☐ Yes ☐ No | ☐ Yes ☐ No | ☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) |
| ***Certification must be submitted** | If "Yes" Unit Packaging wgt. / No. per Container | If "Yes" Package wgt. / No. per Container | |

| 3. Location of Net Contents Information | 4. Size(s) Retail Container | 5. Location of Label Directions |
|---|---|---|
| ☐ Label ☐ Container | | ☐ On Label ☐ On Labeling accompanying product |

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Other _____ ☐ Paper glued ☐ Stenciled

## Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

| Name | Title | Telephone No. (Include Area Code) |
|---|---|---|
| Chris Zemanek | Analyst, Registrations | (937) 578-1467 |

**Certification**

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

| 2. Signature The Scotts Company BY: | 3. Title Analyst, Registrations |
|---|---|
| 4. Typed Name Chris Zemanek | 5. Date March 7, 2016 |

*Product ingredient source information may be entitled to confidential treatment*

Form approved. OMB No. 2070-0060, 2070-0057, 2070-0107, 2070-0122, 2070-0164.

United States
**Environmental Protection Agency**
Washington, DC 20460

# Formulator's Exemption Statement

*(40 CFR 152.85)*

| Applicant's Name and Address | EPA File Symbol/Registration Number |
|---|---|
| The Scotts Company<br>d/b/a The Ortho Group<br>Post Office Box 190<br>Marysville, OH 43040 | 239-2721 |
| | Product Name<br>Ortho 13% Bifenthrin MUP |
| | Date of Confidential Statement of Formula *(EPA Form 8570-4)*<br>January 13, 2016 |

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

bifenthrin

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

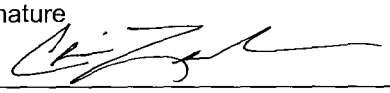
☑ (A) An accurate Confidential Statement of Formula *(EPA FORM 8570-4)* for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

**OR**

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

| | **Source** | |
|---|---|---|
| **Active Ingredient** | **Product Name** | **Registration Number** |
| Bifenthrin | [redacted] | [redacted] |

| Signature | Name and Title | Date |
|---|---|---|
|  | Chris Zemanek, Analyst, Registration | March 7, 2016 |

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 – EPA
Copy 2 - Applicant copy

49230000


***The Scotts Company LLC***
*and Subsidiaries*

September 27, 2013

Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

**ATTN:** **Richard Gebken**
**Insecticide Branch**
**Product Manager 10**

**SUBJECT:** **The Scotts Company d/b/a The Ortho Group**
**Ortho 13% Bifenthrin MUP**
**EPA File Symbol: 239-ETER**
**Request for Waiver of Product Chemistry**

Dear Mr. Gebken:

Per our conversation on September 12, 2013, The Scotts Company d/b/a The Ortho Group is submitting an application to request a waiver for product chemistry, Storage Stability and Corrosion – OPPTS Guidelines 830.6317 and 830.6320 for EPA File Symbol 239-ETER.

As we discussed, we are planning to store this product in potentially two types of packaging, fluorine treated HDPE and 304 stainless. The testing for fluorine treated HDPE is ongoing, and will be submitted upon completion to satisfy OPPTS Guidelines 830.6317 and 830.6320. The waiver request is only for storage in the 304 stainless. Due to the nature of the material, there is no expectation of degradation of the formula or corrosion. A complete rationale is included in the report included with this submission.

I appreciate your help in forwarding this onto chemistry for review. Upon review, please advise if this waiver is acceptable or if we need to go forward with testing for both options.

The enclosed Transmittal Document outlines the materials enclosed to support this submission.

Please contact me at 937-578-5984 or by email at Jane.Rothwell@Scotts.com should you have any questions regarding this submission.

Regards,

Jane Rothwell, Analyst, Regulatory Affairs
Enclosures

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

**DP BARCODE No.:** D415873 **REG. No. /File Symbol No.** 239-ETER **PRODUCT NAME: ORTHO 13 % BIFENTHRIN MUP** **Code(s):** 128825 **Decision No.** 479664 **Action Code:** R310 **Food Use:** YES [X]

**DATE OUT:** 01/07/14

**SUBJECT:** MUP Product Chemistry Review
Product Name: ORTHO 13 % BIFENTHRIN MUP

**FROM:** Indira Gairola, Product Chemistry Team
Technical Review Branch / Registration Division (7505P)

**TO:** BeWanda Alexander/ Richard Gebken PM 10
Insecticide Branch / Registration Division (7505P)

Company Name: THE SCOTTS COMPANY
Formulation Type Insecticide (liquid)

## INTRODUCTION:

The registrant submitted a waiver request for Storage Stability Data and corrosion characteristics for the new MUP "ORTHO 13 % BIFENTHRIN MUP" in a 304 stainless steel container(MRID # 492300-01) Applicant has provided the following justification:

## SUMMARY OF FINDINGS:

This waiver request is in regards to storage stability and corrosion testing only in a 304 stainless steel container type. The formula may also be stored in fluorine-treated HDPE totes., thus a GLP storage stability and corrosion study will be conducted using this material and submitted as a separate report upon completion.

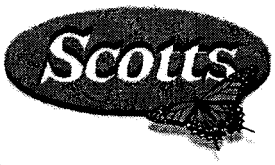
The Ortho 13% Bifenthrin MUP is a solution of bifenthrin. The solubility limit for bifenthrin in the solvents listed on the registration is much higher than the thirteen percent by weight on the registration. Therefore, bifenthrin will remain in solution and formula separation will not occur as is possible with an emulsion or suspension formula.

Furthermore, 304 stainless steel is considered a non-reactive metal. There should not be any interaction between any of the formula components and the 304 stainless steel container. Also, the formula is completely solvent-based without any water present and consists entirely of non-ionic raw materials (meaning even if 304 stainless steel was susceptible, there are no free ionic acid or base groups present to cause corrosion).

Finally, our raw material suppliers ship the solvents used in the formula in stainless steel containers without issue. It is unlikely the components of the formula would interact with the container differently than the individual raw materials do in this case.

## CONCLUSIONS:

TRB will accept the aforementioned request of the applicant, and will review a separate report when submitted .




***The Scotts Company LLC***
*and Subsidiaries*

July 11, 2014

Document Processing Desk (FPL)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

**ATTN:** Richard Gebken
Insecticide Branch
Product Manager 10

**SUBJECT:** Submission of Final Printed Labeling
Ortho 13% Bifenthrin MUP
EPA File Symbol: 239-2721

Dear Mr. Gebken:

The Scotts Company LLC d/b/a The Ortho Group hereafter "Scotts" is submitting a true and accurate representation of the final printed label for the subject product. This representation incorporates the label changes accepted by the Agency in its letter dated January 29, 2014. Please find the following documentation in support of this submission:

- Completed Application for Pesticide Registration/Amendment Form (8570-1);
- Two (2) copies of final printed label

Scotts understands that it may now release product bearing the final printed label represented herein for shipment and in doing so accepts all of the conditions set forth in the Agency's correspondence noted above. Please note that the enclosed master label is a true and accurate representation of the final printed label for the subject product. Scotts reserves the right to execute additional revisions to the final printed label and distribute product so-labeled provided that any such revisions are consistent with the most recent master label accepted by the Agency.

Should you have any questions regarding this submission, please contact me at 937-578-5984 or by email Jane.Rothwell@Scotts.com.

Regards,

Jane Rothwell, Analyst, Regulatory Affairs
Enclosures

*14111 Scottslawn Road Marysville, Ohio 43041 937-644-0011*

*Please read instructions on reverse before completing form.* Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

**EPA** United States **Environmental Protection Agency** Washington, DC 20460

☐ **Registration** ☐ **Amendment** ☒ **Other**

OPP Identifier Number

## Application for Pesticide - Section I

| 1. Company/Product Number | 2. EPA Product Manager | 3. Proposed Classification |
|---|---|---|
| 239-2721 | Richard Gebken | ☒ None ☐ Restricted |
| 4.Company/Product (Name) The Ortho Group / Ortho 13% Bifenthrin MUP | PM# 10 | |

5. Name and Address of Applicant *(Include ZIP Code)*

The Scotts Company d/b/a The Ortho Group
PO Box 190
Marysville, OH 43040

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

## Section II

| | |
|---|---|
| ☐ Amendment - Explain below. | ☒ Final printed labels |
| ☐ Resubmission in response to Agency letter dated | ☐ "Me Too" Application |
| ☐ Notification - Explain below. | ☐ Other - Explain below. |

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
Submission of final printed labeling in response to EPA letter dated January 29, 2014.

## Section III

1. Material This Product Will Be Packaged In:

| Child-Resistant Packaging | Unit Packaging | Water Soluble Packaging | 2. Type of Container |
|---|---|---|---|
| ☐ Yes* ☐ No | ☐ Yes ☐ No | ☐ Yes ☐ No | ☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) bag/ bottle |
| ***Certification must be submitted** | If "Yes" Unit Packaging wgt. / No. per Container | If "Yes" Package wgt. / No. per Container | |

| 3. Location of Net Contents Information | 4. Size(s) Retail Container | 5. Location of Label Directions |
|---|---|---|
| ☐ Label ☐ Container | | ☐ On Label ☐ On Labeling accompanying product |

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Other _____ ☐ Paper glued ☐ Stenciled

## Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

| Name | Title | Telephone No. (Include Area Code) |
|---|---|---|
| Jane Rothwell | Analyst, Regulatory Affairs | (937) 578-5984 |

### Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

| 2. Signature The Scotts Company BY: | 3. Title |
|---|---|
| | Analyst, Regulatory Affairs |
| 4. Typed Name Jane Rothwell | 5. Date: July 11, 2014 |

# Ortho 13% Bifenthrin MUP

**For manufacturing use only**

| ACTIVE INGREDIENT: | BY WT. |
|---|---|
| Bifenthrin:* | 13.0% |
| OTHER INGREDIENTS: | 87.0% |
| TOTAL: | 100.0% |

* Cis isomers 97% minimum; trans isomers 3% maximum.
Ortho 13% Bifenthrin MUP contains 1.0 pounds bifenthrin per gallon.

## KEEP OUT OF REACH OF CHILDREN

# CAUTION

| FIRST AID | |
|---|---|
| **If swallowed** | • Call a poison control call center or doctor immediately for treatment advice.<br>• Have person sip a glass of water if able to swallow.<br>• Do not induce vomiting unless told to by the poison control center or doctor.<br>• Do not give anything by mouth to an unconscious person. |
| **If in eyes:** | • Hold eye open and rinse slowly and gently with water for 15-20 minutes.<br>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.<br>• Call a poison control center or doctor for treatment advice. |
| **If on skin or clothing** | • Take off contaminated clothing<br>• Rinse skin immediately with plenty of water for 15-20 minutes.<br>• Call a poison control center or doctor for treatment advice. |
| **HOTLINE NUMBER** | |
| Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-(800)-225-2883 for Emergency Assistance. | |
| **NOTE TO PHYSICIAN**<br>This product is a pyrethroid. If large amounts have been ingested, the stomach and intestine should be evacuated. Treatment is symptomatic and supportive. Digestible fats, oils or alcohol may increase absorption and should be avoided. | |

**NET CONTENTS:** 5 to 500 gal (18.93 to 1892.71 liters)

### PRECAUTIONARY STATEMENTS
### HAZARDS TO HUMANS

**CAUTION**: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

### ENVIRONMENTAL HAZARDS

This product is toxic to aquatic organisms, including fish and invertebrates.
Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination Systems (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or regional office of the EPA. Do not contaminate water when disposing of equipment wash-waters.

### DIRECTIONS FOR USE

**It is a violation of Federal law to use this product in a manner inconsistent with its labeling.**

This product may be used to formulate products for specific use (s) not listed on the MP label if the formulator, user group, or grower has complied with US EPA data submission requirements regarding the support of such use(s).

**For Use in Manufacturing Only.**
This material requires further mixing before use.
For Formulation Into End Use Products for the Following Uses:

- Non-crop outdoors
- Lawn
- Indoors
- Terrestrial food crops: Broccoli, Brussel sprouts, Chinese broccoli, Chinese cabbage, Cabbage, Cauliflower, Cavalo broccolo, Kohlrabi, Eggplant, Tomatoes, Head lettuce, Peppers (bell and non bell), Green peas, Sugar snap peas, Snow peas, Green beans (Wax beans, Snap beans), Black eye-peas, Cow pea, Chayote, Citron melon, Cucumber, Gourds, Muskmelon, Pumpkin, Squash, Watermelon, Sweet corn, Herbs

## STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Store in original container only. Store in a cool, dry place and avoid excess heat. Carefully open containers. After partial use, replace lids and close tightly. Do not put concentrate or dilute material into food or drink containers. Do not contaminate other pesticides, fertilizers, water, food or feed by storage or disposal.

In case of spill, avoid contact, isolate area and keep out animals and unprotected persons. Confine spills. Call 1-(800)-225-2883 for assistance.

To confine spill: If liquid, dike surrounding area or absorb with sand, cat litter, or commercial clay. If dry material, cover to prevent dispersal. Place damaged package in a holding container. Identify contents.

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate, is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:**
**Nonrefillable container**. Do not reuse or refill this container. Triple rinse container promptly after empyting. Triple rinse as follows:
**(For containers greater than 5 gallons).** Empty the remaining contents into a storage container or a mix tank. Fill the container ¼ full with appropriate solvent (1). Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into a storage container or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

**(For containers 5 gallons or less).** Empty the remaining contents into storage container or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with appropriate solvent (1) and recap. Shake for 10 seconds. Pour rinsate into storage container or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available, or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities. Do not cut or weld metal containers.

**Returnable/Refillable Containers:** Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents into a storage container or mix tank. Triple rinse as follows: Fill the container 10% full with appropriate solvent (1). Agitate vigorously or recirculate solvent with a pump for two minutes. Pour or pump rinsate into storage container or rinsate collection system. Repeat this rinsing procedure two more times.

(1) An appropriate solvent would include a solvent that will dissolve technical material. The rinsate may be used later to formulate a product or may be disposed in accordance with local, state and national environmental laws, rules, standards, and regulations.

Notice: To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this product not in accordance with directions.

IMPORTANT –READ BEFORE USE
Read the entire Directions For Use, Conditions, Disclaimer or Warranties and Limitations of Liability before using this product.
If terms are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following conditions, Disclaimers of Warranties, and Limitations of Liability.

DISCLAIMER AND LIMITATION OF LIABILITY
IMPORTANT NOTICE FROM THE SCOTTS COMPANY LLC D/B/A THE ORTHO GROUP ("THE ORTHO GROUP"). PLEASE READ BEFORE USE.

To the extent consistent with applicable law, user or buyer accepts the conditions, disclaimer of warranties and limitations of liability. Read the entire directions for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once for full refund.

CONDITIONS: The directions for use of this product are believed to be adequate and the user or buyer must always follow the label directions carefully and exercise judgment and caution when using this product.

WARRANTY: This product corresponds to all claims and descriptions set forth on the label and is reasonably fit for the purposes set forth in the directions for use on the label when used in accordance with those directions. This warranty is subject to the provisions of the applicable state law, but makes no other warranties or representations, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label, including not extending to use or handling of this product contrary to proper manufacturing practices and procedures or under abnormal conditions or conditions not reasonably foreseeable to the ORTHO GROUP or to use by mixture, chemical reaction, or formulation with other substances not specifically recommended in writing by the ORTHO GROUP; Buyer assumes all risk of any such use. No agent of The ORTHO GROUP is authorized to make any warranties beyond those contained herein or to modify the warranties contained therein. Subject to the user's or buyer's rights and remedies under the applicable state law, THE ORTHO GROUP disclaims any liability whatsoever for special, incidental or consequential damages resulting form the use or handling of this product.
LIMITIATIONS OF LIABLITY: Subject to the user's or buyer's rights and remedies under the applicable state law, the exclusive remedy of the user or buyer and the liability of THE ORTHO GROUP or its affiliates, for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid by the user or Buyer for the quantity of this product involved or at THE ORTHO GROUP'S election, the replacement of this product. To the extent consistent with applicable law, THE ORTHO GROUP must have prompt notice of any claim so that a timely investigation of buyer's or user's claims can be made. Buyer and all users shall promptly notify Scotts of any claims, whether based on contract, negligence, strict liability other tort or otherwise or be barred from any remedy.

The Scotts Company d/b/a The Ortho Group
P.O. Box 190
Marysville, Ohio 43040
Made in _____

EPA Reg. No. 239-2721
EPA Est. No. 239-MS-1$^{M}$, 239-IA-3$^{I}$, 84175-TX-1$^{B}$, 538-SC-1$^{P}$, 35512-FL-2$^{H}$, 82757-FL-1$^{T}$ 538-OH-2$^{V}$, 82757-MA-2$^{E}$, 35497-OR-1$^{W}$, 9198-AL-1$^{L}$
*Superscript is first letter of lot number.*

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

| EPA Registration Number: | Date of Issuance: |
|---|---|
| 239-2721 | JAN 29 2014 |
| Term of Issuance: Unconditional | |
| Name of Pesticide Product: Ortho 13% Bifenthrin MUP | |

NOTICE OF PESTICIDE:
X Registration
___ Reregistration

(Under FIFRA as amended)

Name and Address of Registrant (include ZIP Code):
The Scotts Company
PO Box 190
Marysville, OH 43040

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is **unconditionally** registered in accordance with FIFRA sec. 3(c)(5). Once a pesticide is registered, however, it is not regarded as permanently acceptable. Registration does not eliminate the need for continual reassessment of pesticides. If the Agency determines that, at any time, additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under FIFRA section (3).

1. You will make the following label changes before you release the product for shipment:

   a) Revise the EPA Registration Number to read "EPA Reg. No. 239-2721."

2. Per 40 CFR 156.10(a)(6), submit one copy of your final printed labeling before releasing the product for shipment. As defined in 40 CFR 152.3, "final printed labeling" means the "label or labeling of the product when distributed or sold". Clearly legible reproductions or photo reductions will be accepted for unusual labels. Note that a clean copy of the master label in most cases does not meet the definition of final printed labeling. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing amended labeling constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

If you have any questions regarding this action, please contact BeWanda Alexander at www.alexander.bewanda@epa.gov or (703) 305-7460.

| Signature of Approving Official: | Date: |
|---|---|
| Richard Gebken Product Manager<br>Insecticide Branch/Registration Division (7505P) | Jan 29, 2014 |

Enclosure

# Ortho 13% Bifenthrin MUP

**For manufacturing use only**

| ACTIVE INGREDIENT: | BY WT. |
|---|---|
| Bifenthrin:* | 13.0% |
| OTHER INGREDIENTS: | 87.0% |
| TOTAL: | 100.0% |

* Cis isomers 97% minimum; trans isomers 3% maximum.

Ortho 13% Bifenthrin MUP contains 1.0 pounds bifenthrin per gallon.

## KEEP OUT OF REACH OF CHILDREN

# CAUTION

| FIRST AID | |
|---|---|
| **If swallowed** | • Call a poison control call center or doctor immediately for treatment advice.<br>• Have person sip a glass of water if able to swallow.<br>• Do not induce vomiting unless told to by the poison control center or doctor.<br>• Do not give anything by mouth to an unconscious person. |
| **If in eyes:** | • Hold eye open and rinse slowly and gently with water for 15-20 minutes.<br>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.<br>• Call a poison control center or doctor for treatment advice. |
| **If on skin or clothing** | • Take off contaminated clothing<br>• Rinse skin immediately with plenty of water for 15-20 minutes.<br>• Call a poison control center or doctor for treatment advice. |
| **HOTLINE NUMBER** | |
| Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-(800)-225-2883 for Emergency Assistance. | |
| **NOTE TO PHYSICIAN**<br>This product is a pyrethroid. If large amounts have been ingested, the stomach and intestine should be evacuated. Treatment is symptomatic and supportive. Digestible fats, oils or alcohol may increase absorption and should be avoided. | |

The Scotts Company d/b/a The Ortho Group
P.O. Box 190
Marysville, Ohio 43040

EPA Reg. No. 239-XXXX
EPA Est. No. 239-XX-XXX
*Superscript is first letter of lot number.*

ACCEPTED
JAN 29 2014
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide Registered under EPA Reg. No. 239-2721

**NET CONTENTS:** 5 to 500 gal (18.93 to 1892.71 liters)

## PRECAUTIONARY STATEMENTS
## HAZARDS TO HUMANS

**CAUTION**: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

## ENVIRONMENTAL HAZARDS

This product is toxic to aquatic organisms, including fish and invertebrates.
Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination Systems (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or regional office of the EPA. Do not contaminate water when disposing of equipment wash-waters.

## DIRECTIONS FOR USE

**It is a violation of Federal law to use this product in a manner inconsistent with its labeling.**

This product may be used to formulate products for specific use (s) not listed on the MP label if the formulator, user group, or grower has complied with US EPA data submission requirements regarding the support of such use(s).

**For Use in Manufacturing Only.**
This material requires further mixing before use.
For Formulation Into End Use Products for the Following Uses:

- Non-crop outdoors
- Lawn
- Indoors
- Terrestrial food crops: Broccoli, Brussel sprouts, Chinese broccoli, Chinese cabbage, Cabbage, Cauliflower, Cavalo broccolo, Kohlrabi, Eggplant, Tomotoes, Head lettuce, Peppers (bell and non bell), Green peas, Sugar snap peas, Snow peas, Green beans (Wax beans, Snap beans), Black eye-peas, Cow pea, Chayote, Citron melon, Cucumber, Gourds, Muskmelon, Pumpkin, Squash, Watermelon, Sweet corn, Herbs

## STORAGE AND DISPOSAL

**Do not contaminate water, food, or feed by storage or disposal.**

**PESTICIDE STORAGE:** Store in original container only. Store in a cool, dry place and avoid excess heat. Carefully open containers. After partial use, replace lids and close tightly. Do not put concentrate or dilute material into food or drink containers. Do not contaminate other pesticides, fertilizers, water, food or feed by storage or disposal.

**In case of spill, avoid contact, isolate area and keep out animals and unprotected persons. Confine spills. Call 1-(800)-225-2883 for assistance.**
To confine spill: If liquid, dike surrounding area or absorb with sand, cat litter, or commercial clay. If dry material, cover to prevent dispersal. Place damaged package in a holding container. Identify contents.

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate, is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:**
**Nonrefillable container**. Do not reuse or refill this container. Triple rinse container promptly after empyting Triple rinse as follows:
**(For containers greater than 5 gallons).** Empty the remaining contents into a storage container or a mix tank. Fill the container ¼ full with appropriate solvent (1). Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into a storage container or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

**(For containers 5 gallons or less).** Empty the remaining contents into storage container or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with appropriate solvent (1) and recap. Shake for 10 seconds. Pour rinsate into storage container or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available, or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities. Do not cut or weld metal containers.

**Returnable/Refillable Containers:** Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents into a storage container or mix tank. Triple rinse as follows: Fill the container 10% full with appropriate solvent (1). Agitate vigorously or recirculate solvent with a pump for two minutes. Pour or pump rinsate into storage container or rinsate collection system. Repeat this rinsing procedure two more times.

(1) An appropriate solvent would include a solvent that will dissolve technical material. The rinsate may be used later to formulate a product or may be disposed in accordance with local, state and national environmental laws, rules, standards, and regulations.

Notice: To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this product not in accordance with directions.

## IMPORTANT –READ BEFORE USE

Read the entire Directions For Use, Conditions, Disclaimer or Warranties and Limitations of Liability before using this product.
If terms are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following conditions, Disclaimers of Warranties, and Limitations of Liability.

## DISCLAIMER AND LIMITATION OF LIABILITY

IMPORTANT NOTICE FROM THE SCOTTS COMPANY LLC D/B/A THE ORTHO GROUP ("THE ORTHO GROUP"). PLEASE READ BEFORE USE.

To the extent consistent with applicable law, user or buyer accepts the conditions, disclaimer of warranties and limitations of liability. Read the entire directions for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once for full refund.

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WARRANTY: This product corresponds to all claims and descriptions set forth on the label and is reasonably fit for the purposes set forth in the directions for use on the label when used in accordance with those directions. This warranty is subject to the provisions of the applicable state law, but makes no other warranties or representations, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label, including not extending to use or handling of this product contrary to proper manufacturing practices and procedures or under abnormal conditions or conditions not reasonably foreseeable to the ORTHO GROUP or to use by mixture, chemical reaction, or formulation with other substances not specifically recommended in writing by the ORTHO GROUP; Buyer assumes all risk of any such use. No agent of The ORTHO GROUP is authorized to make any warranties beyond those contained herein or to modify the warranties contained therein. Subject to the user's or buyer's rights and remedies under the applicable state law, THE ORTHO GROUP disclaims any liability whatsoever for special, incidental or consequential damages resulting form the use or handling of this product.

LIMITIATIONS OF LIABLITY: Subject to the user's or buyer's rights and remedies under the applicable state law, the exclusive remedy of the user or buyer and the liability of THE ORTHO GROUP or its affiliates, for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid by the user or Buyer for the quantity of this product involved or at THE ORTHO GROUP'S election, the replacement of this product. To the extent consistent with applicable law, THE ORTHO GROUP must have prompt notice of any claim so that a timely investigation of buyer's or user's claims can be made. Buyer and all users shall promptly notify Scotts of any claims, whether based on contract, negligence, strict liability other tort or otherwise or be barred from any remedy.

# Ortho 13% Bifenthrin MUP

**For manufacturing use only**

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|---|---|
| Bifenthrin:* | 13.0% |
| OTHER INGREDIENTS: | 87.0% |
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**HOTLINE NUMBER**

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The Scotts Company d/b/a The Ortho Group
P.O. Box 190
Marysville, Ohio 43040

EPA Reg. No. 239-XXXX
EPA Est. No. 239-XX-XXX
*Superscript is first letter of lot number.*

**NET CONTENTS:** 5 to 500 gal (18.93 to 1892.71 liters)

## PRECAUTIONARY STATEMENTS
## HAZARDS TO HUMANS

**CAUTION**: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

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LIMITIATIONS OF LIABLITY: Subject to the user's or buyer's rights and remedies under the applicable state law, the exclusive remedy of the user or buyer and the liability of THE ORTHO GROUP or its affiliates, for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid by the user or Buyer for the quantity of this product involved or at THE ORTHO GROUP'S election, the replacement of this product. To the extent consistent with applicable law, THE ORTHO GROUP must have prompt notice of any claim so that a timely investigation of buyer's or user's claims can be made. Buyer and all users shall promptly notify Scotts of any claims, whether based on contract, negligence, strict liability other tort or otherwise or be barred from any remedy.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

26/NOV/2013

MEMORANDUM

Subject: Acute Toxicity Review for EPA File Symbol 239-ETER

| | |
|---|---|
| Name of Pesticide Product: | Ortho 13% Bifenthrin MUP |
| EPA File Symbol: | 239-ETER |
| DP Barcode: | D413496 |
| Decision No.: | 479664 |
| Action Code: | R310 |
| PC Code: | 128825 (bifenthrin) |

From: Eugenia McAndrew, Biologist
Technical Review Branch
Registration Division (7505P)

To: BeWanda Alexander, RM Team 10
Insecticide Branch
Registration Division (7505P)

Applicant: The Scotts Company D/B/A The Ortho Group
P.O. Box 190
Marysville, Ohio 443040

FORMULATION FROM LABEL:

| Active Ingredient(s): | % by wt. |
|---|---|
| Bifenthrin | 13.0 |
| Other Ingredient(s): | 87.0 |
| Total: | 100.0% |

**ACTION REQUESTED:** The Risk Manager requests a review of six acute toxicity studies submitted to support registration of the proposed product, EPA File Symbol 239-ETER.

**BACKGROUND:** The Scotts Company has submitted six acute toxicity studies (MRID Nos. 491477-01 to -06) to support the registration of the proposed product, Ortho 13% Bifenthrin MUP, EPA File Symbol 239-ETER. The submission also includes a basic CSF and alternate CSFs A and B which must be reviewed and accepted by the TRB Product Chemistry Team.

**GLP:** Yes

**DEVIATIONS:** None

**LABELING:**

**PRODUCT ID #:** 000239-02721

**PRODUCT NAME:** Ortho 13% Bifenthrin MUP

**PRECAUTIONARY STATEMENTS**

**SIGNAL WORD:** CAUTION

**Hazards to Humans and Domestic Animals:**

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. [Wear protective eyewear.]*

*[Protective eyewear may be specified, if appropriate.]

**First Aid:**

If swallowed:
-Call a poison control center or doctor immediately for treatment advice.
-Have person sip a glass of water if able to swallow.
-Do not induce vomiting unless told to by a poison control center or doctor.
-Do not give anything by mouth to an unconscious person.

If in eyes:
-Hold eye open and rinse slowly and gently with water for 15-20 minutes.
-Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
-Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

## DATA EVALUATION RECORD

**Product Reg. No.:** 239-ETER
**Product Name:** Ortho 13% Bifenthrin MUP

| | | | | |
|---|---|---|---|---|
| **1. DP BARCODE:** 413496 | | | | |
| **2. PC CODE:** 128825 | | | | |
| **3. CURRENT DATE:** November 26, 2013 | | | | |
| **4. TEST MATERIAL:** Ortho 13% Bifenthrin MUP (30*5406); Batch # 839-22; 13% Bifenthrin; density - 0.903 g/mL; clear, light brown liquid; administered as received) | | | | |
| **Study/Species/Lab Study # /Date** | **MRID** | **Results** | **Tox Cat** | **Core Grade** |
| Acute oral toxicity / rat<br>Product Safety Labs<br>Study #35882/April 26, 2013<br>OCSPP 870.1100; OECD 425 | 49147701 | $LD_{50}$ Females = 886.7 mg/kg<br>(95% CI of 183.9 - 10900 mg/kg)<br>Sponsor supplied estimate of $LD_{50}$ of 377 mg/kg; starting dose of 119 mg/kg used<br>11 animals tested at 119 (2 animals), 380 (3 animals), 1190 (4 animals) or 5000 ( 2 animals) mg/kg<br><br>mortality: 1/3 at 380 mg/kg, 2/3 at 1190 mg/kg and 2/2 at 5000 mg/kg<br><br>clinical signs:<br>119 mg/kg (2 animals): nasal discharge, hyperactivity, reduced fecal volume in 1 animal with recovery by day 2; body weight gains<br><br>380 mg/kg (3 animals): decedent had nasal discharge, hyperactivity, reduced fecal volume and tremors; surviving animals had similar symptoms but recovered by day 2; body weight gains<br><br>1190 mg/kg (4 animals): decedents had hyperactivity, tremors, nasal discharge and/or irregular respiration; survivors had reduced fecal volume, hyperactivity, | III | A |

| | | | | |
|---|---|---|---|---|
| | | tremors, nasal discharge and/or soft feces with recovery by day 2;<br>body weight gains<br><br>5000 mg/kg (2 animals): both decedents had hyperactivity, tremors, and/or nasal discharge<br><br>gross abnormalities at necropsy:<br>119 mg/kg: none<br>380 mg/kg: discoloration of the stomach and intestines and distended stomach in decedent only<br>1190 mg/kg: discoloration of the lungs and/or liver and detention of the intestines and/or stomach in two decedents only<br>5000 mg/kg: discoloration of the lungs, distention of the intestines and/or stomach | | |
| Acute dermal toxicity / rat<br>Product Safety Labs<br>Study #35883/April 15, 2013<br>OCSPP 870.1200; OECD 402 | 49147702 | $LD_{50}$ > 5000 mg/kg (both sexes)<br>mortality: 1 female was euthanized for humane reasons within 1 day of test substance administration; this animal had a self-inflicted wound following attempts to remove the patch<br>clinical signs: 8/9 survivors had abnormal gait, tremors, nasal discharge, ocular discharge, ano-genital staining, oral discharge, hunched posture, hyperactivity and/or hypoactivity with recovery by day 14<br>body weight gains and no gross abnormalities at necropsy in survivors | IV | A |

| | | | | |
|---|---|---|---|---|
| Acute inhalation toxicity / rat<br>Product Safety Labs<br>Study #35884/May 14, 2013<br>OCSPP 870.1300; OECD 403 | 49147703 | $LC_{50}$ > 5.10 mg/L (both sexes)<br>MMAD: 2.19, 2.26 µm<br>GSD: 2.11, 2.15<br>mortality: none<br>clinical signs: irregular respiration, tremors, abnormal gait, moist rales, nasal discharge, facial staining, reduced fecal volume, hunched posture, ano-genital staining, ocular discharge, and/or hypoactivity in all animals with recovery by day 10 except for abnormal gait which persisted in 1 animal through day 14; all animals lost weight by day 1 but gained weight thereafter; no gross abnormalities at necropsy | IV | A |
| Primary eye irritation / rabbit<br>Product Safety Labs<br>Study #35885/April 15, 2013<br>OCSPP 870.2400; OECD 405 | 49147704 | 3 males tested<br>ocular anesthetic used<br>no corneal opacity or iritis noted; positive conjunctival redness noted in 1 eye at 1 hr and in all eyes at 24 hrs; no positive scores at 48 hrs and all eyes clear by 72 hours; positive conjuctival discharge noted in 2/3 eyes at 1 hr only | III | A |
| Primary dermal irritation / rabbit<br>Product Safety Labs<br>Study #35886/April 15, 2013<br>OCSPP 870.2500; OECD 404 | 49147705 | PDI = 1.1<br>2 males and 1 female tested<br>very slight erythema at all sites at 24 hrs; very slight erythema at 1 site and well defined erthema at 2 sites at 48 and 72 hrs; animals free of irritation by day 10; desquamation at all sites on days 7 and 10 | IV | A |
| Dermal sensitization /guinea pig<br>Product Safety Labs<br>Study #35887/April 26, 2013<br>OCSPP 870.2600; OECD 406 | 49147706 | Not a sensitizer<br>appropriate positive control provided | -- | A |

**Core Grade Key: A =Acceptable, S = Supplementary, W = Waived, U = Unacceptable, D = Data Gap**

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

**DP BARCODE No.:** D413497 **REG. No. /File Symbol No**. 239-ETER **PRODUCT NAME: ORTHO 13 % BIFENTHRIN MUP Code(s)**: 128825 **Decision No.** 479664 **Action Code**: R310 **Food Use**: YES [X]

**DATE OUT**: 12/19/13

**SUBJECT**: MUP Product Chemistry Review
Product Name: ORTHO 13 % BIFENTHRIN MUP

**FROM:** Indira Gairola, Product Chemistry Team 12/19/13
Technical Review Branch / Registration Division (7505P) 12/19/13

**TO**: BeWanda Alexander/ Richard Gebken PM 10
Insecticide Branch / Registration Division (7505P)

**Company Name**: THE SCOTTS COMPANY
**Formulation Type** Insecticide (liquid)

**INTRODUCTION**:

The registrant submitted an application for registration of the new MUP "ORTHO 13 % BIFENTHRIN MUP". Registrant is submitting product chemistry data with (MRID # 491477-07 to -08) basic CSF and alternate formulations A & B all dated 05/09/13 for the proposed subject product.
TRB has been asked to determine the acceptability of the aforementioned product chemistry data and CSF.

**SUMMARY OF FINDINGS:**

1. Name of Active Ingredient(s): Bifenthrin (13.0%).

2. Has the registrant claimed substantial similarity to a registered product

   No [X] Yes [ ] [ ] NA; if yes give the registration number of the cited product.

3. All of the source materials of the active ingredient are derived from registered sources-
   [X] Yes [ ] No

4. All inert ingredients have been screened by IIAB and found to be approved for the proposed

labeled food uses.

5. Confidential Statement of Formula(s):

[X] Proposed Basic dated 05/09/13 [NA] Resubmitted date:

[X] Proposed Alternate A&B both dated 05/09/13

Proposed Alternate comply with 40CFR§152.43: [X] Yes; [ ] No [ ] [NA]

6. Product label

a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2)

[X] Yes; [ ] No; if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs. other ingredient?)
[X] Yes; [ ] No; if not, explain below:

| | |
|---|---|
| Metallic equivalent: | [X] NA |
| Isomeric ratios | [X] YES cis isomers 97% minimum, trans isomers 3.0% maximum |
| Soluble Arsenic | [X] NA |
| Acid Equivalent | [X] NA |

b. Health related sub statements: Product contains?

| | |
|---|---|
| Petroleum distillate at > 10%: | [ ] Yes [X] No [ ] NA |
| Methanol at > 4%: | [ ] Yes [X] No [ ] NA |
| Sodium nitrate/Sodium nitrite: | [ ] Yes [X] No [ ] NA |

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?
[ ] Yes No [X]
Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?
[ ] Yes, [ ] No; [X] NA; if not, explain below:

d. Label requires an additional Storage and Disposal statement: [ ] Yes [X] No; if yes Explain below:

7 Group **A**: Product Chemistry Data: TRB's determination of the acceptability of the data for the proposed product is listed in the tables below:

| Guideline No. | Study Title | | Data submitted | | TRB's Assessment of Data | MRID Nos. |
|---|---|---|---|---|---|---|
| | | | Yes | No | | |
| 830.1550 | Product Identity & Composition | | X | | A | 491477-07 |
| 830.1600 | Description of materials used to produce the product | | X | | A | 491477-07 |
| 830.1650 | Description of formulation process | | X | | A | 491477-07 |
| 830.1670 | Discussion on the formation of impurities | | X | | A | 491477-07 |
| 830.1700 | Preliminary analysis | | | NA | | CSF 05/09/13 |
| 830.1750 | Certified limits (158.350) | Standard certified Limits | X | | A | |
| | | Proposed Limits | | | A | |
| | | Justification for wider limits | | | | |
| 830.1800 | Enforcement analytical method | | | X | A | 491477-07 |

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable, U = Upgradeable.

8. Group **B:**

| Guideline No. | Study Title | Value or Qualitative Description | TRB's Assessment of Data | MRID Nos. |
|---|---|---|---|---|
| 830.6303 | Physical State | liquid | A | 491477-08 |
| 830.6315 | Flammability | >230°F | A | 491477-08 |
| 830.6314 | Oxi/ Red | Does not contain any Oxidi/Reducing agents | A | 491477-08 |
| 830.6316 | Explodability | Does not contain any explosive ingredients | NA | |
| 830.7000 | pH | 4.65-5.59 (dilution in 5% ethanol) | A | 491477-08 |
| 830.7100 | Viscosity | 8.88 cps | A | 491477-08 |
| 830.7300 | Density (units) | 0.9210 g/mL, CSF /.7.8-8.5 g/mL | A | 491477-08 |

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable, U = Upgradeable.

**CONCLUSIONS:**

TRB has reviewed the basic CSF and alternate formulation A &B all dated 05/09/13 and product chemistry data corresponding to guideline 830 series, group A & group B for the proposed subject product "ORTHO 13 % BIFENTHRIN MUP" and concluded

1. The aforementioned CSFs for the subject product and data corresponding to 830 series group A Guideline (product identity and composition) are acceptable.

2. Data submitted corresponding to 830 series group B product chemistry are acceptable.

3. Applicant is required to submit one-year storage stability data (guideline 830.6317) and corrosion Characteristics (guideline 830.6320) studies for 0, 3, 6, 9, and 12 month intervals. The results from both study types must be submitted

4. The proposed label was screened as it pertains to the product chemistry requirements.

5 . The final review of the proposed label and uses are the purview of the PM team.

.

49230000

*The Scotts Company LLC*

*and Subsidiaries*

September 27, 2013

Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

**ATTN:** **Richard Gebken**
**Insecticide Branch**
**Product Manager 10**

**SUBJECT:** **The Scotts Company d/b/a The Ortho Group**
**Ortho 13% Bifenthrin MUP**
**EPA File Symbol: 239-ETER**
**Request for Waiver of Product Chemistry**

Dear Mr. Gebken:

Per our conversation on September 12, 2013, The Scotts Company d/b/a The Ortho Group is submitting an application to request a waiver for product chemistry, Storage Stability and Corrosion – OPPTS Guidelines 830.6317 and 830.6320 for EPA File Symbol 239-ETER.

As we discussed, we are planning to store this product in potentially two types of packaging, fluorine treated HDPE and 304 stainless. The testing for fluorine treated HDPE is ongoing, and will be submitted upon completion to satisfy OPPTS Guidelines 830.6317 and 830.6320. The waiver request is only for storage in the 304 stainless. Due to the nature of the material, there is no expectation of degradation of the formula or corrosion. A complete rationale is included in the report included with this submission.

I appreciate your help in forwarding this onto chemistry for review. Upon review, please advise if this waiver is acceptable or if we need to go forward with testing for both options.

The enclosed Transmittal Document outlines the materials enclosed to support this submission.

Please contact me at 937-578-5984 or by email at Jane.Rothwell@Scotts.com should you have any questions regarding this submission.

Regards,

Jane Rothwell, Analyst, Regulatory Affairs
Enclosures

*14111 Scottslawn Road Marysville, Ohio 43041 937-644-0011*

**TRANSMITTAL DOCUMENT**

1. **NAME AND ADDRESS OF SUBMITTER:**

   The Scotts Company d/b/a The Ortho Group
   PO Box 190
   Marysville, Ohio 43040

2. **REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED:**

   **Ortho 13% Bifenthrin MUP - EPA File Symbol: 239-ETER**

   Submission of Storage Stability and Corrosion Waiver Request

3. **TRANSMITTAL DATE: September 27, 2013**

4. **LIST OF SUBMITTED STUDIES:**

| Volume | Study Title | Guideline Number | MRID |
|---|---|---|---|
| I | Administrative Materials<br>Cover Letter<br>Transmittal Document<br>EPA Form 8570-1, Application for Pesticide Registration | N/A | |
| 11 | Ortho 13% Bifenthrin MUP, EPA File Symbol 239-ETER, S-17623; Physical and Chemical Characteristics: Corrosion and Storage Stability; Author: Jack Schmansky; September 27, 2013, Study No. SS-322, 4 pages | 830.6320<br>830.6317 | 49230001 |

**Company Official:** Jane Rothwell, Analyst, Regulatory Affairs

**Signature:** _____

**Company Name:** The Scotts Company d/b/a The Ortho Group

**Company Contact:** Jane Rothwell

**Phone Number:** 937-578-5984

# Memorandum

Date: 10/30/13

To: PM 10, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

**We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.**

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:
- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

Conditional Data

SS + CC

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 23, 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

THE SCOTTS COMPANY
14111 SCOTTSLAWN ROAD
MARYSVILLE, OH 43041

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 18-OCT-13. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.


**The Scotts Company LLC**
*and Subsidiaries*

September 27, 2013

Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

**ATTN:** **Richard Gebken**
**Insecticide Branch**
**Product Manager 10**

**SUBJECT:** **The Scotts Company d/b/a The Ortho Group**
**Ortho 13% Bifenthrin MUP**
**EPA File Symbol: 239-ETER**
**Request for Waiver of Product Chemistry**

Dear Mr. Gebken:

Per our conversation on September 12, 2013, The Scotts Company d/b/a The Ortho Group is submitting an application to request a waiver for product chemistry, Storage Stability and Corrosion – OPPTS Guidelines 830.6317 and 830.6320 for EPA File Symbol 239-ETER.

As we discussed, we are planning to store this product in potentially two types of packaging, fluorine treated HDPE and 304 stainless. The testing for fluorine treated HDPE is ongoing, and will be submitted upon completion to satisfy OPPTS Guidelines 830.6317 and 830.6320. The waiver request is only for storage in the 304 stainless. Due to the nature of the material, there is no expectation of degradation of the formula or corrosion. A complete rationale is included in the report included with this submission.

I appreciate your help in forwarding this onto chemistry for review. Upon review, please advise if this waiver is acceptable or if we need to go forward with testing for both options.

The enclosed Transmittal Document outlines the materials enclosed to support this submission.

Please contact me at 937-578-5984 or by email at Jane.Rothwell@Scotts.com should you have any questions regarding this submission.

Regards,

Jane Rothwell, Analyst, Regulatory Affairs
Enclosures

**TRANSMITTAL DOCUMENT**

1. **NAME AND ADDRESS OF SUBMITTER:**

   The Scotts Company d/b/a The Ortho Group
   PO Box 190
   Marysville, Ohio 43040

2. **REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED:**

   **Ortho 13% Bifenthrin MUP - EPA File Symbol: 239-ETER**

   Submission of Storage Stability and Corrosion Waiver Request

3. **TRANSMITTAL DATE: September 27, 2013**

4. **LIST OF SUBMITTED STUDIES:**

| Volume | Study Title | Guideline Number | MRID |
|---|---|---|---|
| I | Administrative Materials<br>Cover Letter<br>Transmittal Document<br>EPA Form 8570-1, Application for Pesticide Registration | N/A | |
| 11 | Ortho 13% Bifenthrin MUP, EPA File Symbol 239-ETER, S-17623; Physical and Chemical Characteristics: Corrosion and Storage Stability; Author: Jack Schmansky; September 27, 2013, Study No. SS-322, 4 pages | 830.6320<br>830.6317 | 49230001 |

**Company Official:** Jane Rothwell, Analyst, Regulatory Affairs

**Signature:** _____

**Company Name:** The Scotts Company d/b/a The Ortho Group

**Company Contact:** Jane Rothwell

**Phone Number:** 937-578-5984

# Administrative Materials

*Please read instructions on reverse before completing form.* Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

**EPA** United States **Environmental Protection Agency** Washington, DC 20460

☐ Registration ☐ Amendment ☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

| 1. Company/Product Number | 2. EPA Product Manager | 3. Proposed Classification |
|---|---|---|
| 239-ETER | Richard Gebken | ☒ None ☐ Restricted |
| 4.Company/Product (Name) The Ortho Group / Ortho 13% Bifenthrin MUP | PM# 10 | |

5. Name and Address of Applicant *(Include ZIP Code)*

The Scotts Company d/b/a The Ortho Group
PO Box 190
Marysville, OH 43040

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

## Section II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated
☐ Notification - Explain below.
☐ Final printed labels
☐ "Me Too" Application
☒ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
Submission of waiver request for Storage Stability and Corrosion- OPPTS Guidelines 830.6317 and 830.6320. See Cover letter for details.

## Section III

1. Material This Product Will Be Packaged In:

| Child-Resistant Packaging | Unit Packaging | Water Soluble Packaging | 2. Type of Container |
|---|---|---|---|
| ☐ Yes* ☒ No | ☐ Yes ☒ No | ☐ Yes ☒ No | ☐ Metal ☒ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) bag/ bottle |
| **Certification must be submitted* | If "Yes" Unit Packaging wgt. / No. per Container | If "Yes" Package wgt. / No. per Container | |

| 3. Location of Net Contents Information | 4. Size(s) Retail Container | 5. Location of Label Directions |
|---|---|---|
| ☒ Label ☐ Container | 5 gal to 500 gal | ☒ On Label ☐ On Labeling accompanying product |

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☒ Other _____ ☒ Paper glued ☐ Stenciled

## Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

| Name | Title | Telephone No. (Include Area Code) |
|---|---|---|
| Jane Rothwell | Analyst, Regulatory Affairs | (937) 578-5984 |

**Certification**

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

C. Date Application Received **(Stamped)**

| 2. Signature The Scotts Company BY: | 3. Title |
|---|---|
| 4. Typed Name Jane Rothwell | 5. Date: September 27, 2013 |

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 18, 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

THE SCOTTS COMPANY
PO.BOX : 190
MARYSVILLE, OH 43040

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 10-JUN-13. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

# Completion of 21-Day Content Screen

PM- 10

EPA Reg. #(File Symbol) 239-ETER

Decision # D 479664

Data package delivered to you on 6/24/13.
(date)

Jacket/Mini-jacket will be transferred to you today.
(Pick up from Document Center)

Thank you,

Registration Division's 21-Day Content Team

# Memorandum

Date: 06/19/13

To: PM 21, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

**We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN**.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:
- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 18, 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

THE SCOTTS COMPANY
PO.BOX : 190
MARYSVILLE, OH 43040

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 10-JUN-13. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

*The Scotts Company LLC*
*and Subsidiaries*

June 5, 2013

Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

**ATTN:** **Richard Gebken**
**Insecticide Branch**
**Product Manager 10**

**SUBJECT:** **The Scotts Company LLC d/b/a The Ortho Group**
**Ortho 13% Bifenthrin MUP**
**EPA File Symbol: 239-NEW**

Dear Mr. Gebken:

The Scotts Company LLC d/b/a The Ortho Group (hereafter "Scotts") is submitting an application for the registration of a new manufacturing use product, Ortho 13% Bifenthrin MUP, containing the registered active ingredient bifenthrin.

We believe this action should be processed as a PRIA Category R-310 decision, including a fee of $ 4807 and a 7-month decision time. Note- The PRIA request was inadvertently entered as 538-NEW (Scotts Company No.). It should have been Company No. 239 (Ortho). The category and fee are correct.

To satisfy acute toxicity and product chemistry, we are submitting our own Group A and Group B product chemistry and acute toxicity studies. A basic confidential statement of formula (CSF) and alternate CSFs A and B are included with this submission.

The results of the acute toxicity studies were as follows:

| Guideline number | Study | Results | Category |
|---|---|---|---|
| 870.1100 | Acute oral | $LD_{50}$ is 886.7 mg/kg (greater than 500 less than 5000 mg/kg) | III |
| 870.1200 | Acute dermal | $LD_{50}$ greater than 5000 mg/kg | IV |
| 870.1300 | Acute inhalation | $LC_{50}$ is greater than 5.10 mg/L in male and female rats | IV |
| 870.2400 | Primary eye irritation | Mildly irritating. Irritation cleared by 72 hours | III |
| 870.2500 | Primary skin irritation | Slightly irritating at 72 hours | III |
| 870.2600 | Skin Sensitization | Not sensitizing | IV |

Based on the results of the acute toxicity, the label is a CAUTION Signal word. The Storage and Disposal section of this label has been modified to accommodate cleaning the container with a diluent other than water.

Scott's qualifies for the Formulator's Exemption for this action. The enclosed Transmittal Document outlines the materials enclosed to support this application.

Please contact me at 937-578-5984 or by email at Jane.Rothwell@Scotts.com should you have any questions regarding this application.

Regards,

Jane Rothwell, Analyst, Regulatory Affairs
Enclosures

**TRANSMITTAL DOCUMENT**

1. **NAME AND ADDRESS OF SUBMITTER:**

   The Scotts Company LLC d/b/a The Ortho Group
   PO Box 190
   Marysville, Ohio 43040

2. **REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED:**

   Application for registration of new product: **Ortho 13% Bifenthrin MUP**

   **EPA File Symbol: 239-NEW**

3. **TRANSMITTAL DATE: June 5, 2013**

4. **LIST OF SUBMITTED STUDIES:**

| Volume | Study Title | Guideline Number | MRID |
|---|---|---|---|
| I | Administrative Materials<br><br>Cover Letter<br><br>Transmittal Document<br><br>Receipt of Payment of PRIA fee; R310 , 7 month review: Note- The PRIA payment references 538-NEW; the amount and category are correct, the company number should have been 239-NEW.<br><br>EPA Form 8570-1, Application for Pesticide Registration<br><br>Product label (5 copies)<br><br>EPA Form 8570-4, Confidential Statement of Formula- BASIC (2 copies) (dated 5/09/2013)<br><br>EPA From 8570-4, Confidential Statement of Formula ALTERNATES A and B (2 copies each)(dated 5/09/2013)<br><br>EPA Form 8570-27, Formulator's Exemption<br><br>EPA Form 8570-34, Certification with Respect to Data Citation<br><br>EPA Form 8570-35, Data Matrix (EPA and public versions) | N/A | |
| II | Ortho 13% Bifenthrin MUP (30*5406); Acute Oral Toxicity Up and Down Procedure in Rats; Author: Carolyn Lowe, LATG; April 26, 2013; Product Safety Labs; SS # 35882; 17 pages (3 copies) | 870.1100 | **49147701** |

| | | | |
|---|---|---|---|
| III | Ortho 13% Bifenthrin MUP (30*5406); Acute Dermal Toxicity Study in Rats; Author: Carolyn Lowe, LATG; April 15, 2013; Product Safety Labs; SS # 35883; 16 pages; (3 copies) | 870.1200 | 49147702 |
| IV | Ortho 13% Bifenthrin MUP (30*5406); Acute Inhalation Toxicity Study in Rats; Author: Carolyn Lowe, LATG; April 15, 2013, Amended May 14, 2013; Product Safety Labs; SS # 35884; 24 pages; (3 copies) | 870.1300 | 49147703 |
| V | Ortho 13% Bifenthrin MUP (30*5406); Primary Eye Irritation Study in Rabbits; Author: Carolyn Lowe, LATG; April 15, 2013; Product Safety Labs; SS # 35885; 15 pages; (3 copies) | 870.2400 | 49147704 |
| VI | Ortho 13% Bifenthrin MUP (30*5406); Primary Skin Irritation Study in Rabbits; Author: Carolyn Lowe, LATG; April 15, 2013; Product Safety Labs; SS # 35886; 15 pages; (3 copies) | 870.2500 | 49147705 |
| VII | Ortho 13% Bifenthrin MUP (30*5406); Dermal Sensitization Study in Guinea Pigs (Buehler Method); Author: Carolyn Lowe, LATG; April 26, 2013; Product Safety Labs; SS # 35887; 24 pages; (3 copies) | 870.2600 | 49147706 |
| VIII | Product Identity, Composition, and Analysis for product; Ortho 13% Bifenthrin MUP, 239-NEW; Author: Jason Hoy; The Scotts Company LLC; Study # SS-322A; May 9, 2013; 10 pages (plus 4 pages Confidential Attachment) ; (3 copies) | 830.1550<br>830.1600<br>830.1650<br>830.1670<br>830.1750<br>830.1800 | 49147707 |
| IX | Ortho 13% Bifenthrin MUP, EPA Reg. No. 239-New,S-17623; Physical and Chemical Characteristics: Color, Physical State, Odor, Oxidation/Reduction Potential, pH, Specific Gravity, Flammability, Viscosity, Corrosion and Storage Stability; Author: Jack Schmansky; May 10, 2013; SS # 322; The Scotts Company LLC, 17 pages; (3 copies) | 830.6302<br>830.6303<br>830.6304<br>830.6314<br>830.7000<br>830.7300<br>830.6315 | 49147708 |

| | | | |
|---|---|---|---|
| | | 830.7100<br>830.6320<br>830.6317 | |

**Company Official:** Jane Rothwell, Analyst, Regulatory Affairs

**Signature:** _____

**Company Name:** The Scotts Company LLC d/b/a The Ortho Group

**Company Contact:** Jane Rothwell

**Phone Number:** 937-578-5984

# PDMS Studies Log In Sheet

MRID 491477

Logged In — Initial/Date: 6-11

Submission Type: FFS/Normal/6(a)(2)

Resubmission: ☐

Page Count: First ☒ Second ☑

Electronic Submission: Yes/No

S# 936533

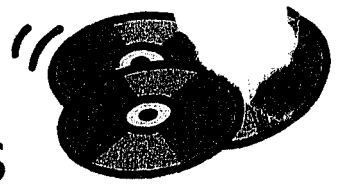
PM/RM 10 Study Count 8

Submitter: 239

Admin. Numbers: 239-ETER

Comments:

Special Instructions:



# NEW APPLICATIONS

**DATE:** JUN 10 2013

**FILE REG NUMBER:** 239-ETER

**FEP (OPPIN ENTRY)** LV JUN 11 2013

**(Initial & Date)**

**FILE ROOM:** _____

**(Initial & Date)**

**SIG:** _____

**(Initial & Date)**

**FILE ROOM:** _____

**(Initial & Date)**

**ASSIGN TO PM: AD**_____ **RD** ✓ 10 **BPPD**_____

_____ **JACKET TO SHELF (DATA)**

REVISED 11/28/12

# 21-Day Screen Completed by Contractor

## 21-Day Expires on 7/1/13

**Jacket #** 239-ETER
**MRID#** 491477

**Content Screen:** Recommend to **Pass**/Fail

**11-3 Review:** **Pass**/Fail/NA

**Overall Status:** Recommend to **Pass**/Fail

# Transfer This Jacket to:

Steve Schaible

1D

# PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 6-10-13

Experts In-Processing Signature: B.B. Date 6-12-13 Fee Paid: Yes ✓

Division management contacted on issues No_____ Yes_____ Date_____

| EPA Reg. Number: 239-ETER | EPA Receipt Date: 6-10-13 |
|---|---|

| | Items for Review | | | Yes | No | N/A* |
|---|---|---|---|---|---|---|
| 1 | **Application Form** (EPA Form 8570-1) signed & complete including package type | | | X | | |
| 2 | **Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4) | | | X | | |
| | a) All inerts, including fragrances, approved for the proposed uses (see Footnote A) | **yes** X | **no** | | | |
| 3 | **Certification with Respect to Citation of Data** (EPA Form 8570-34) completed and signed (N/A if 100% repack) | | | X | | |
| | Certificate and data matrix consistent | | | X | | |
| | If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B) | **yes** | **no** | | | |
| | If applicable, is there a letter of Authorization for exclusive use only. | | | | | |
| 4 | **Formulator's Exemption Statement** (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical) | | | X | | |
| 5 | **Data Matrix** (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack) | | | X | | |
| | a) Selective Method (Fee category experts use) | **yes** X | **no** | | | |
| | b) Cite-All (Fee category experts use) | | | | | |
| | c) Applicant owns all data (Fee category experts use) | | | | | |
| 6 | **5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)** | | | X | | |
| 7 | **Is the data package consistent with PR Notice 86-5** | | | X | | |
| 8 | **Notice of Filing included with petitions** | | | | | X |

| | | | | |
|---|---|---|---|---|
| 9 | **If applicable for conventional applications, <u>reduced risk rationale</u>** | | | X |
| 10 | **<u>Required Data</u> and/or data waivers. See Footnote C.** | | | |
| | a) List study (or studies) not included with application | | | |

**Comments:**

X AI + Comp. added

X CSF: Approved under 40 CFR 180.920

X Data package approved.

X Jackal approved.

MRID: 491477

lk 703-347-8[illegible]

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

**Unapproved Inerts Identified on CSFs**

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or

3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

# R 310

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGAI). Must submit Group A and B product chemistry data for each proposed product unless it's a 100% identical (repack): YES or NO (circle one)

| Guideline No. | Group A: Product Chemistry Data Study Title | EP Data Submitted | | MP Data Submitted | | TGAI | |
|---|---|---|---|---|---|---|---|
| | | Yes | No | Yes | No | Yes | No |
| 830.1550 | Product Identity & Composition | ✓ | | | | | |
| 830.1600 | Description of materials used to produce the product | ✓ | | | | | |
| 830.1650 | Description of formulation process | ✓ | | | | | |
| 830.1670 | Discussion on the formation of impurities | ✓ | | | | | |
| 830.1700 | Preliminary analysis | | X | | | | |
| 830.1750 | Certified limits (158.345) | ✓ | | | | | |
| 830.1800 | Enforcement analytical method | ✓ | | | | | |

| Guideline No. | Group B: Product Chemistry Data Study Title | EP Data Submitted | | MP Data Submitted | | TGAI | |
|---|---|---|---|---|---|---|---|
| | | Yes | No | Yes | No | Yes | No |
| 830.6302 | Color | ✓ | | | | | |
| 830.6303 | Physical State | ✓ | | | | | |
| 830.6304 | Odor | ✓ | | | | | |
| 830.6313 | Stability to normal and elevated temperatures metal and metal ions | | | | | | |
| 830.6314 | Oxidation/Reduction (Chemical incompatibility) | ✓ | | | | | |
| 830.6315 | Flammability | ✓ | | | | | |
| 830.6316 | Explodability | | X | | | | |
| 830.6317 | Storage stability | ✓ | | | | | |
| 830.6319 | Miscibility | | X | | | | |
| 830.6320 | Corrosion Characteristics | ✓ | | | | | |
| 830.6321 | Dielectric Breakdown Voltage | | X | | | | |
| 830.7000 | pH | ✓ | | | | | |
| 830.7050 | UV/ Visible Absorption | | | | | | |
| 830.7100 | Viscosity | ✓ | | | | | |
| 830.7200 | Melting Point | | | | | | |
| 830.7220 | Boiling Point | | | | | | |
| 830.7300 | Density | ✓ | | | | | |
| 830.7370 | Dissociation Constant | | | | | | |
| 830.7550 | Partition Coefficient | | | | | | |
| 830.7840 | Water Solubility | | | | | | |
| 830.7950 | Vapor Pressure | | | | | | |

Grayed out = data not required

R 310

New products must either: 1) supply the product specific acute toxicity 6 pack data (listed below), or 2) provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

| Guideline No. | Acute toxicity (6 pack) Study Title | Data submitted | | Cited | |
|---|---|---|---|---|---|
| | | Yes | No | Yes | No |
| 870.1100 | Acute Oral (LD50) | ✓ | | | |
| 870.1200 | Acute Dermal (LD50) | ✓ | | | |
| 870.1300 | Acute Inhalation (LC50) | ✓ | | | |
| 870.2400 | Acute Eye Irritation | ✓ | | | |
| 870.2500 | Acute Dermal Irritation | ✓ | | | |
| 870.2600 | Dermal Sensitization | ✓ | | | |

Efficacy – which guideline is used depends on the proposed label use

| Guideline No. | Study Title | Data submitted | | Cited | | Comments |
|---|---|---|---|---|---|---|
| | | Yes | No | Yes | No | |
| 810.3100 | Soil Treatments for Imported Fire Ants | | | | | |
| 810.3200 | Livestock, Poultry, Fur and Wool-Bearing Animal Treatments | | | | | |
| 810.3300 | Treatments to Control Pests of Humans and Pets | | | | | |
| 810.3400 | Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments | | | | | |
| 810.3500 | Premises Treatments | | | | | |
| 810.3600 | Structural Treatments | | | | | |
| 810.3800 | Methods for Efficacy Testing of Termite Baits | | | | | |

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 11, 2013

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-479664
EPA File Symbol or Registration Number: 239-ETER
Product Name: ORTHO 13% BIFENTHRIN MUP
EPA Receipt Date: 10-Jun-2013
EPA Company Number: 239
Company Name: THE SCOTTS COMPANY

JANE ROTHWELL
THE SCOTTS COMPANY
D/B/A THE ORTHO GROUP
PO Box 190
MARYSVILLE, OH 43040

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code R310:

NEW END-USE OR MANUFACTURING USE PRODUCT WITH REGISTERED SOURCE(S) OF ACTIVE INGREDIENT(S);INCLUDES PRODUCTS CONTAINING TWO OR MORE REGISTERED ACTIVE INGREDIENTS PREVIOUSLY COMBINED IN OTHER REGISTERED PRODUCTS;REQUIRES REVIEW OF DATA PACKAGE WITHIN RD ONLY;INCLUDES DATA AND/OR WAIVERS OF DATA FOR ONLY:;PRODUCT CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);CHILD RESISTANT PACKAGING;

No additional payment is due at this time. If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

# Fee for Service

{936533*~

This package includes the following

- (•) New Registration
- ( ) Amendment

[x] Studies? [ ] Fee Waiver?

[ ] volpay % Reduction: ___

for Division

- ( ) AD
- ( ) BPPD
- (•) RD

Risk Mgr. 10

Receipt No. S- 936533

EPA File Symbol/Reg. No. 239-ETER

Pin-Punch Date: 6/10/2013

[ ] This item is NOT subject to FFS action.

## Action Code:

Requested: R310

Granted: R310

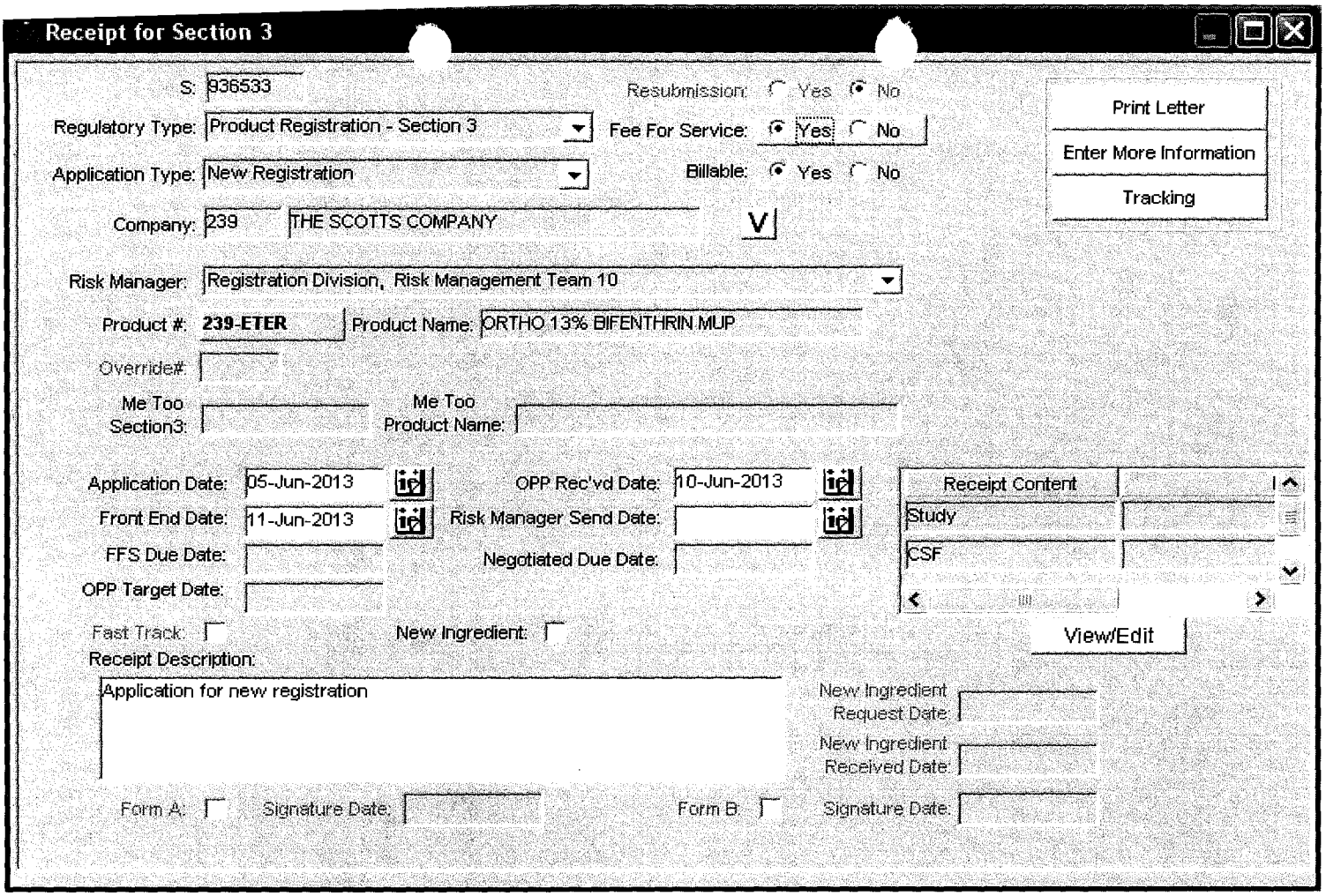
Amount Due: $ 4,807

## Parent/Child Decisions:

[ ] Inert Cleared for Intended Use [ ] Uncleared Inert in Product

Reviewer: Jennifer Gaines Date: 6/11/13

Remarks:


Receipt for Section 3
S: 936533
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: New Registration
Billable: Yes No
Company: 239 THE SCOTTS COMPANY
Print Letter
Enter More Information
Tracking
Risk Manager: Registration Division, Risk Management Team 10
Product #: 239-ETER
Product Name: ORTHO 13% BIFENTHRIN MUP
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 05-Jun-2013
OPP Rec'vd Date: 10-Jun-2013
Front End Date: 11-Jun-2013
Risk Manager Send Date:
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Study
CSF
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
Application for new registration
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

ScottsMiracle-Gro

# Pay.gov Payment Confirmation: PRIA Service Fees

**paygovadmin@mail.doc.twai.gov** <paygovadmin@mail.doc.twai.gov> Tue, Jun 4, 2013 at 7:25 AM
To: "melissa.mclain@scotts.com" <melissa.mclain@scotts.com>

Your payment has been submitted to Pay.gov and the details are below. If you have any questions or you wish to cancel this payment, please contact Pay.gov Customer Service by phone at (800) 624-1373 or by email at pay.gov.clev@clev.frb.org.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25B1C2EO
Agency Tracking ID: 74458728921
Transaction Type: Sale
Transaction Date: Jun 4, 2013 7:25:33 AM

Account Holder Name: Connie Christian
Transaction Amount: $4,807.00
Billing Address: 14111 Scottslawn Rd.
City: Marysville
State/Province: OH
Zip/Postal Code: 43041
Country: USA
Card Type: Visa
Card Number: **********3991

Decision Number:
Registration Number: 538-NEW
Company Name: The Scotts Company
Company Number: 538
Action Code: R- 310

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

*Please read instructions on reverse before completing form.* Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

**EPA** United States **Environmental Protection Agency** Washington, DC 20460

☒ **Registration** ☐ **Amendment** ☐ **Other**

OPP Identifier Number

## Application for Pesticide - Section I

| 1. Company/Product Number | 2. EPA Product Manager | 3. Proposed Classification |
|---|---|---|
| The Scotts Company d/b/a The Ortho Group / 239-NEW | Richard Gebken | |
| 4.Company/Product (Name) The Ortho Group / Ortho 13% Bifenthrin MUP | PM# 10 | ☒ None ☐ Restricted |

5. Name and Address of Applicant *(Include ZIP Code)*

The Scotts Company d/b/a The Ortho Group
PO Box 190
Marysville, OH 43040

☐ *Check if this is a new address*

6. **Expedited Review**. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

## Section II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated
☐ Notification - Explain below.
☐ Final printed labels
☐ "Me Too" Application
☒ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
Submission of new product-Ortho 13% Bifenthrin MUP. PRIA Category R310; 7 month review time.
Email: Jane.Rothwell@Scotts.com

## Section III

1. Material This Product Will Be Packaged In:

| Child-Resistant Packaging | Unit Packaging | Water Soluble Packaging | 2. Type of Container |
|---|---|---|---|
| ☐ Yes* ☒ No | ☐ Yes ☒ No | ☐ Yes ☒ No | ☐ Metal ☒ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) bag/ bottle |
| ***Certification must be submitted** | If "Yes" Unit Packaging wgt. / No. per Container | If "Yes" Package wgt. / No. per Container | |

| 3. Location of Net Contents Information | 4. Size(s) Retail Container | 5. Location of Label Directions |
|---|---|---|
| ☒ Label ☐ Container | 5 gal to 500 gal | ☒ On Label ☐ On Labeling accompanying product |

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☒ Other _____ ☒ Paper glued ☐ Stenciled

## Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

| Name | Title | Telephone No. (Include Area Code) |
|---|---|---|
| Jane Rothwell | Analyst, Regulatory Affairs | (937) 578-5984 |

### Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

| 2. Signature The Scotts Company BY: | 3. Title |
|---|---|
| | Analyst, Regulatory Affairs |
| 4. Typed Name Jane Rothwell | 5. Date: June 5, 2013 |

*The Scotts Company LLC*
*and Subsidiaries*

June 5, 2013

Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

**ATTN:** **Richard Gebken**
**Insecticide Branch**
**Product Manager 10**

**SUBJECT:** **The Scotts Company LLC d/b/a The Ortho Group**
**Ortho 13% Bifenthrin MUP**
**EPA File Symbol: 239-NEW**

Dear Mr. Gebken:

The Scotts Company LLC d/b/a The Ortho Group (hereafter "Scotts") is submitting an application for the registration of a new manufacturing use product, Ortho 13% Bifenthrin MUP, containing the registered active ingredient bifenthrin.

We believe this action should be processed as a PRIA Category R-310 decision, including a fee of $ 4807 and a 7-month decision time. Note- The PRIA request was inadvertently entered as 538-NEW (Scotts Company No.). It should have been Company No. 239 (Ortho). The category and fee are correct.

To satisfy acute toxicity and product chemistry, we are submitting our own Group A and Group B product chemistry and acute toxicity studies. A basic confidential statement of formula (CSF) and alternate CSFs A and B are included with this submission.

The results of the acute toxicity studies were as follows:

| Guideline number | Study | Results | Category |
|---|---|---|---|
| 870.1100 | Acute oral | $LD_{50}$ is 886.7 mg/kg (greater than 500 less than 5000 mg/kg) | III |
| 870.1200 | Acute dermal | $LD_{50}$ greater than 5000 mg/kg | IV |
| 870.1300 | Acute inhalation | $LC_{50}$ is greater than 5.10 mg/L in male and female rats | IV |
| 870.2400 | Primary eye irritation | Mildly irritating. Irritation cleared by 72 hours | III |
| 870.2500 | Primary skin irritation | Slightly irritating at 72 hours | III |
| 870.2600 | Skin Sensitization | Not sensitizing | IV |

Based on the results of the acute toxicity, the label is a CAUTION Signal word. The Storage and Disposal section of this label has been modified to accommodate cleaning the container with a diluent other than water.

Scott's qualifies for the Formulator's Exemption for this action. The enclosed Transmittal Document outlines the materials enclosed to support this application.

Please contact me at 937-578-5984 or by email at Jane.Rothwell@Scotts.com should you have any questions regarding this application.

Regards,

Jane Rothwell, Analyst, Regulatory Affairs
Enclosures

**TRANSMITTAL DOCUMENT**

1. **NAME AND ADDRESS OF SUBMITTER:**

   The Scotts Company LLC d/b/a The Ortho Group
   PO Box 190
   Marysville, Ohio 43040

2. **REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED:**

   Application for registration of new product: **Ortho 13% Bifenthrin MUP**

   **EPA File Symbol: 239-NEW**

3. **TRANSMITTAL DATE: June 5, 2013**

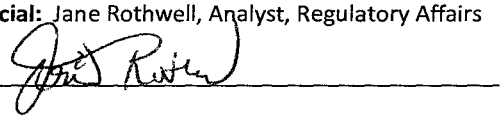
4. **LIST OF SUBMITTED STUDIES:**

| Volume | Study Title | Guideline Number | MRID |
|---|---|---|---|
| I | Administrative Materials<br><br>Cover Letter<br><br>Transmittal Document<br><br>Receipt of Payment of PRIA fee; R310 , 7 month review: Note- The PRIA payment references 538-NEW; the amount and category are correct, the company number should have been 239-NEW.<br><br>EPA Form 8570-1, Application for Pesticide Registration<br><br>Product label (5 copies)<br><br>EPA Form 8570-4, Confidential Statement of Formula-BASIC (2 copies) (dated 5/09/2013)<br><br>EPA From 8570-4, Confidential Statement of Formula ALTERNATES A and B (2 copies each)(dated 5/09/2013)<br><br>EPA Form 8570-27, Formulator's Exemption<br><br>EPA Form 8570-34, Certification with Respect to Data Citation<br><br>EPA Form 8570-35, Data Matrix (EPA and public versions) | N/A | |
| II | Ortho 13% Bifenthrin MUP (30*5406); Acute Oral Toxicity Up and Down Procedure in Rats; Author: Carolyn Lowe, LATG; April 26, 2013; Product Safety Labs; SS # 35882; 17 pages (3 copies) | 870.1100 | |

| | | | |
|---|---|---|---|
| III | Ortho 13% Bifenthrin MUP (30*5406); Acute Dermal Toxicity Study in Rats; Author: Carolyn Lowe, LATG; April 15, 2013; Product Safety Labs; SS # 35883; 16 pages; (3 copies) | 870.1200 | |
| IV | Ortho 13% Bifenthrin MUP (30*5406); Acute Inhalation Toxicity Study in Rats; Author: Carolyn Lowe, LATG; April 15, 2013, Amended May 14, 2013; Product Safety Labs; SS # 35884; 24 pages; (3 copies) | 870.1300 | |
| V | Ortho 13% Bifenthrin MUP (30*5406); Primary Eye Irritation Study in Rabbits; Author: Carolyn Lowe, LATG; April 15, 2013; Product Safety Labs; SS # 35885; 15 pages; (3 copies) | 870.2400 | |
| VI | Ortho 13% Bifenthrin MUP (30*5406); Primary Skin Irritation Study in Rabbits; Author: Carolyn Lowe, LATG; April 15, 2013; Product Safety Labs; SS # 35886; 15 pages; (3 copies) | 870.2500 | |
| VII | Ortho 13% Bifenthrin MUP (30*5406); Dermal Sensitization Study in Guinea Pigs (Buehler Method); Author: Carolyn Lowe, LATG; April 26, 2013; Product Safety Labs; SS # 35887; 24 pages; (3 copies) | 870.2600 | |
| VIII | Product Identity, Composition, and Analysis for product; Ortho 13% Bifenthrin MUP, 239-NEW; Author: Jason Hoy; The Scotts Company LLC; Study # SS-322A; May 9, 2013; 10 pages (plus 4 pages Confidential Attachment) ; (3 copies) | 830.1550<br>830.1600<br>830.1650<br>830.1670<br>830.1750<br>830.1800 | |
| IX | Ortho 13% Bifenthrin MUP, EPA Reg. No. 239-New,S-17623; Physical and Chemical Characteristics: Color, Physical State, Odor, Oxidation/Reduction Potential, pH, Specific Gravity, Flammability, Viscosity, Corrosion and Storage Stability; Author: Jack Schmansky; May 10, 2013; SS # 322; The Scotts Company LLC, 17 pages; (3 copies) | 830.6302<br>830.6303<br>830.6304<br>830.6314<br>830.7000<br>830.7300<br>830.6315 | |

| | | | |
|---|---|---|---|
| | | 830.7100<br>830.6320<br>830.6317 | |

**Company Official:** Jane Rothwell, Analyst, Regulatory Affairs

**Signature:** 

**Company Name:** The Scotts Company LLC d/b/a The Ortho Group

**Company Contact:** Jane Rothwell

**Phone Number:** 937-578-5984

Form approved. OMB No. 2070-0060, 2070-0057, 2070-0107, 2070-0122, 2070-0164.

United States
**Environmental Protection Agency**
Washington, DC 20460

# Formulator's Exemption Statement

*(40 CFR 152.85)*

| Applicant's Name and Address | EPA File Symbol/Registration Number |
|---|---|
| The Scotts Company<br>d/b/a The Ortho Group<br>Post Office Box 190<br>Marysville, OH 43040 | 239-NEW |
| | Product Name<br>Ortho 13% Bifenthrin MUP |
| | Date of Confidential Statement of Formula *(EPA Form 8570-4)*<br>May 9, 2013 |

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

bifenthrin

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☑ (A) An accurate Confidential Statement of Formula *(EPA FORM 8570-4)* for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

**OR**

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

| | **Source** | |
|---|---|---|
| **Active Ingredient** | **Product Name** | **Registration Number** |
| bifenthrin | [redacted] | [redacted] |
| Signature | Name and Title<br>Jane Rothwell, Analyst, Regulatory Affairs | Date<br>June 5, 2013 |

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 – EPA
Copy 2 - Applicant copy

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M Street, S.W.**
**WASHINGTON, D.C. 20460**

Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice**: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20430. Do not send the form to this address.

## DATA MATRIX

| | | |
|---|---|---|
| Date June 5, 2013 | EPA Reg. No./File Symbol 239-NEW | Page 1 of 2 |
| Applicant's/Registrant's Name & Address: **The Scotts Company LLC d\b\a The Ortho Group**<br>**P.O. Box 190**<br>**Marysville, OH 43040** | Product<br>**Ortho 13% Bifenthrin MUP** | |
| Ingredient(s): Bifenthrin: CAS # 82657-04-3 | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 830.1550 | Product Identity and Composition | submitted | The Scotts Co. (#239) | OWN | |
| 830.1600 | Description of the Materials Used to Produce the Product | submitted | The Scotts Co. (#239) | OWN | |
| 830.1620 | Description of production process | Not required | | Not required | |
| 830.1650 | Description of the formulation process | submitted | The Scotts Co. (#239) | OWN | |
| 830.1670 | Discussion of Formation of Impurities | submitted | The Scotts Co. (#239) | OWN | |
| 830.1700 | Preliminary Analysis | Not required | | Not required | |
| 830.1750 | Certified Limits | submitted | The Scotts Co. (#239) | OWN | |
| 830.1800 | Enforcement Analytical Method | submitted | The Scotts Co. (#239) | OWN | |
| 830.1900 | Submittal of samples | Not required | | Not required | |
| 830.6302 | Color | submitted | The Scotts Co. (#239) | OWN | |
| 830.6303 | Physical State | submitted | The Scotts Co. (#239) | OWN | |
| 830.6304 | Odor | submitted | The Scotts Co. (#239) | OWN | |
| 830.6313 | Stability | Not required | | Not required | |
| 830.6314 | Oxidation/reduction:chemical incompatibility | submitted | The Scotts Co. (#239) | OWN | |
| 830.6315 | Flammability | submitted | The Scotts Co. (#239) | OWN | |
| 830.6316 | Explodability | Not required | | Not required | |
| 830.6317 | Storage Stability | ongoing | The Scotts Co. (#239) | OWN | |
| 830.6319 | Miscibility | Not required | | Not required | |
| 830.6320 | Corrosion Characteristics | ongoing | The Scotts Co. (#239) | OWN | |
| 830.6321 | Dielectric Breakdown Voltage | Not required | | Not required | |
| 830.7000 | pH | submitted | The Scotts Co. (#239) | OWN | |
| 830.7050 | UV/Visible light absorption | Not required | | Not required | |
| 830.7100 | Viscosity | submitted | The Scotts Co. (#239) | OWN | |
| 830.7200 | Melting point/melting range | Not required | | Not required | |
| 830.7220 | Boiling Point | Not required | | Not required | |

| Signature | Name and Title: Jane Rothwell, Analyst, Regulatory Affairs | June 5, 2013 |
|---|---|---|

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## DATA MATRIX

| Date June 5, 2013 | EPA Reg. No./File Symbol 239-NEW | Page 2 of 2 |
|---|---|---|
| Applicant's/Registrant's Name & Address: **The Scotts Company LLC d\b\a The Ortho Group**<br>**P.O. Box 190**<br>**Marysville, OH 43040** | Product<br>**Ortho 13% Bifenthrin MUP** | |

Ingredient(s): Bifenthrin: CAS # 82657-04-3

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 830.7300 | Density/Relative Density/Bulk Density | submitted | The Scotts Co. (#239) | OWN | |
| 830.7370 | Dissociation Constant | Not required | | Not required | |
| 830.7520 | Particle size, fiber length, &diameter distribution | Not required | | Not required | |
| 830.7550/7560/7570 | Partition Coefficient | Not required | | Not required | |
| 830.7840/7860 | Water Solubility | Not required | | Not required | |
| 830.7950 | Vapor Pressure | Not required | | Not required | |
| 870.1100 | Acute Oral Toxicity | submitted | The Scotts Co. (#239) | OWN | |
| 870.1200 | Acute Dermal Toxicity | submitted | The Scotts Co. (#239) | OWN | |
| 870.1300 | Acute Inhalation Toxicity | submitted | The Scotts Co. (#239) | OWN | |
| 870.2400 | Primary Eye Irritation | submitted | The Scotts Co. (#239) | OWN | |
| 870.2500 | Primary Dermal Irritation | submitted | The Scotts Co. (#239) | OWN | |
| 870.2600 | Skin Sensitization | submitted | The Scotts Co. (#239) | OWN | |
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| Signature | Name and Title: Jane Rothwell, Analyst, Regulatory Affairs | June 5, 2013 |
|---|---|---|

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**Certification with Respect to Citation of Data**

| | |
|---|---|
| Applicant's/Registrant's Name, Address and Telephone Number<br>The Scotts Company LLC, d/b/a The Ortho Group<br>P.O. Box 190, Marysville, OH 43040 (937)-578-5984 | EPA Registration Number/ File Symbol<br>239-NEW |
| Active Ingredient(s) and/or representative test compound(s):<br>bifenthrin (CAS # 82657-04-3) | Date<br>June 5, 2013 |
| General use pattern(s) (list all those claimed for this product using 40 CFR Part 158)<br>Terrestrial, residential outdoor, indoor | Product Name<br>Ortho 13% Bifenthrin MUP |

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT** (Check one method only)

| | |
|---|---|
| ☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose). | ☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used). |

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data Call-In Notice is supported by all data submitted or cited in the application for registration, the form for reregistration, or this Data Call-In response. In addition, if cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original submitter or that I have obtained the written permission of the original submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the written permission of the original data submitter to use this study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

**I certify that the statements I have made on this form and all attachments to it are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.**

| Signature | Date | Typed or Printed Name and Title |
|---|---|---|
| | June 5, 2013 | Jane Rothwell, Analyst, Regulatory Affairs |

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| | | |
|---|---|---|
| Date June 5, 2013 | EPA Reg. No./File Symbol 239-NEW | Page 1 of 2 |
| Applicant's/Registrant's Name & Address: **The Scotts Company LLC d\b\a The Ortho Group**<br>**P.O. Box 190**<br>**Marysville, OH 43040** | Product<br>**Ortho 13% Bifenthrin MUP** | |
| Ingredient(s): Bifenthrin: CAS # 82657-04-3 | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| [redacted] | | | The Scotts Co. (#239) | OWN | |
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| | | | | Not required | |
| | | | The Scotts Co. (#239) | OWN | |
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| | | | | Not required | |
| | | | | Not required | |

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|---|---|---|
| **Signature** | **Name and Title: Jane Rothwell, Analyst, Regulatory Affairs** | **June 5, 2013** |

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Ingredient(s): Bifenthrin: CAS # 82657-04-3

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
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| Signature | Name and Title: Jane Rothwell, Analyst, Regulatory Affairs | June 5, 2013 |
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